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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/502,498	02/11/2000	Andrzej Kilian	I91106407C2	5251
7590	07/18/2002			
RICHARD C. PEET			EXAMINER	
FOLEY & LARDNER				
WASHINGTON HARBOUR			WALICKA, MALGORZATA A	
3000 K STREET NW SUITE 500				
WASHINGTON, DC 20007			ART UNIT	PAPER NUMBER
			1652	18
DATE MAILED: 07/18/2002				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Applicant No .	Applicant(s)
	09/502,498 Examiner Malgorzata A. Walicka	KILIAN ET AL. Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on May 15, 2002.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 16,18,19 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 16,18,19 and 22 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>14</u> . | 6) <input checked="" type="checkbox"/> Other: <i>See Continuation Sheet</i> . |

Continuation of Attachment(s) 6). Other: copies of the relevant pages of the US patent No. 6,166,178, copies of SEQ ID NO:46 and 45 of the instant application, and alignment of SEQ ID NO:46 with SEQ ID NO: 613 of the US patent 6,166,178.

The examiner acknowledges Amendment and Reply under 37 CFR §1.111, filed on May 15, 2002, as paper 16. The amendments to the claims and specification have been entered as requested. Claim 17 is cancelled. Claims 16, 18, 19, and 22 are pending in the application and are the subject of this Office Action.

### Detailed Office Action

#### **1. Rejections**

##### **1. 1. 35 U.S.C. 112, second paragraph**

Rejection of claims 19 and 22 made in the previous Office Action, paper No. 13 are withdrawn because the claims have been amended.

##### **1.2. 35 U.S.C. 112, first paragraph**

###### **1.2.1. Lack of written description**

Amended claims 19 and 22 remain rejected under 35 U.S.C. 112, first paragraph, for the reason indicated in the previous Office Action, paper No. 13.

Applicants arguments presented in paper No. 16 have been considered but are found not persuasive. The amended claim 19 is depending on claim 16, and not 18, as stated in the REMARKS. Claim 16 is directed to any splice variant of human telomerase. Therefore, the fragment of splice variant claimed in the amended claim 19 lacks the written description of structure.

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New rejection for lack of written description

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amino acid sequence SEQ ID NO: 46 is not encoded by the polynucleotide sequence of SEQ ID NO: 45; see the attached copies of sequences. SEQ ID NO: 46 has in position 18 threonine, while codon No. 18 of encoding SEQ ID NO: 45 is encoding tyrosine. Please correct the error. In addition, Applicants are required to examine other amino acid sequences of claim 18 and their encoding sequences for possible discrepancies.

*1. 2.2. Scope of enablement*

Amended claims 16, 19 and 22 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the variant of human telomerase described by SEQ ID NO: 46 and its fragments that may be encoded by the introns (SEQ ID NO: 18, 23, 25, 27, 29, 30, 32 and 33), does not reasonably provide enablement for any splice variant of human telomerase, its fragments or fragments that are 10-100 amino acids in length.

**1.3. 35 USC section 102**

Amended claim 16, 18, 19, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Cech et al in the US Patent No. 6,166,178, issued December 26, 2000, with priority to Oct. 1996.

Claim 16 of the instant application is directed to an isolated protein comprising any splice variant of the human telomerase protein. Claim 19 is directed to any fragment of any splice variant of human telomerase. Claim 22 is directed to any 10-100 amino acid long fragment of any splice variant of the human telomerase.

As to claim 16, Cech et al. disclose a human telomerase splice variant, delta-182 variant (column 13, line 67 and column 20, line 39), having amino acid sequence SEQ ID NO: 5 that is encoded by SEQ ID NO: 4. Although Cech et al do not use the term "splice variant" they contemplate that polypeptides such as delta 182 variant may play a biological role in nature (e.g., in regulation of telomerase expression) and find use as therapeutics (e.g. as dominant-negative products that inhibit function of wild-type proteins).

In respect to claim 19, Cech et al teach that human telomerase fragments (polypeptides) are one of the embodiments of their invention, (column 7, line 38 and further, also column 77, line 42). The fragments may be used as inhibitors of telomerase activity and as such used in pharmaceutical compositions.

In respect to claim 22, Cech et al teach fragments of the delta 182 variant (column 21, line 8), i.e. motifs T, 1, 2, and A. As may be seen from Fig. 1 and 2 of the patent, the length of the motifs is in the range 10-100 amino acids.

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Claim 18 is directed to a protein comprising a sequence that is at least 75% identical to SEQ ID NO: 46. SEQ ID NO: 613 of the US patent 6,166,178 comprises amino acid sequence that is in 98.7% identical to SEQ ID NO:46; see the enclosed sequence search.

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**3. Conclusion**

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Małgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

Art Unit 1652

Assistant Patent Examiner



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